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7310. LIMITATIONS OF BENEFICIARIES' LIABILITY FOR CLAIMS FOR PHYSICIAN AND SUPPLIER SERVICES - ADVANCE BENEFICIARY NOTICE (ABN) STANDARDS.

Following are the standards for use by carriers in implementing the Advance Beneficiary Notice (ABN) requirements of several statutory provisions which limit beneficiaries' financial liability for certain denied claims, which currently include the Refund Requirements (RR) provisions in §§1834(a)(18), 1834(j)(4), 1842(l), and 1879(h) of the Social Security Act (the Act) and the Limitation On Liability (LOL) provisions in §1879(a)-(c) of the Act. Following are several frequently asked questions (FAQs) about different ABN implications of Limitation On Liability and the Refund Requirements.

Q.1. What are the main differences between "Limitation On Liability" (LOL) and the "Refund Requirements" (RR)?

A.1. LOL and RR are both financial liability provisions of the Medicare law. LOL is provided under §1879(a)-(c) of the Social Security Act (the Act) for all Part A services and all assigned claims for Part B services. RR is provided under §1879(h) for assigned claims for medical equipment and supplies. RR is also provided for unassigned claims for medical equipment and supplies under §§ 1834(a)(18) and 1834(j)(4) and for unassigned claims for physicians' services under §1842(l) of the Act. LOL provides for program payment for denied claims in certain circumstances, and for beneficiary indemnification in certain circumstances. RR does not provide for either program payment or indemnification, but does provide that physicians and suppliers, if held liable under RR provisions, must make refunds to beneficiaries of any amounts collected.

Q.2. So, ABNs are used under both LOL and RR? The same ABNs?

A.2. Yes, CMS-R-131 forms may be used under both LOL and RR. An ABN-G would be the appropriate ABN for all RR situations as well as for all LOL situations. ABN-L may be used where LOL applies in a claim for laboratory tests. There should be no occasion when using an ABN-L would be appropriate under RR since payment for laboratory tests is claimed on an assigned basis, meaning that only LOL might apply.

Q.3. Is there some difference in the significance of the beneficiary's signature on an ABN depending on whether LOL or RR applies?

A.3. Yes. In order for a beneficiary to be held liable under RR, that is, under §§ 1834(a)(18), 1834(j)(4), 1842(l), or 1879(h) of the Act, it is necessary that the beneficiary sign the ABN. All the RR provisions require, not only that the beneficiary be notified, but also that the beneficiary agree to pay in order for the beneficiary to be held liable. Thus, an unsigned ABN cannot be used to shift liability to a beneficiary when RR applies. Under LOL, a beneficiary signature is not an absolute requirement. The LOL provision requires only that the beneficiary be properly notified; there is no explicit requirement for an agreement to pay. Therefore, our instructions provide for the situation in which a beneficiary receives an ABN, refuses to sign it but still demands to receive the services specified on the ABN. In that case, the physician or supplier can annotate the form, with the signature of a witness, that the beneficiary received notice but refused to sign the form and can submit the claim with a GA modifier indicating that an ABN was given (see MCM §7310.3.F.2).

Q.4. The ABN forms include these sentences in Option 1: "If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have." If LOL does not require the beneficiary to agree to make payment, why are these sentences included?

A.4. The LOL provisions require only that the beneficiary be notified (i.e., agreement to pay is not a requirement); nevertheless, since the beneficiary's signature on an ABN indicating receipt can, and very likely will, result in his or her financial liability under the LOL provisions, the approved ABN form includes agreement to pay language in all cases, as a matter of full disclosure. Consumer testing indicated that beneficiaries appreciated this information and considered it important and necessary information for making an informed consumer decision. Furthermore, not including this information on ABNs given in LOL

applicable situations could easily mislead beneficiaries to think that they have a third option, viz., to receive the services and not accept liability; that is not a genuine option under LOL. Under LOL, a beneficiary who is properly notified and who receives a service which is subsequently denied payment for the reasons cited on the ABN can be held liable, whether or not the beneficiary agreed to make payment. This fact is a significant difference between LOL and RR.

7310.1 General.--

A. Basic Requirements for ABNs.--An ABN is a written notice a physician or supplier gives to a Medicare beneficiary before items or services are furnished when the physician or supplier believes that Medicare probably or certainly will not pay for some or all of the items or services on the basis of one of the following statutory exclusions: §1862(a)(1) [e.g., medical necessity, mammography, pap smear, pelvic exam, glaucoma, prostate cancer, and colorectal cancer screening tests]; §1834(a)(17)(B), violation of the prohibition on unsolicited telephone contacts for medical equipment and supplies; §1834(j)(1), medical equipment and supplies supplier number requirements not met; or the medical equipment and/or supplies is denied in advance under §1834(a)(15). The only other applicable bases of denial for which ABNs are applicable (viz., §1862(a)(9) custodial care; §1879(g)(1) homebound and intermittent denials for home health care and §1879(g)(2) hospice patient is not terminally ill) are unlikely to apply in a Part B situation. The purpose of the ABN is to inform a Medicare beneficiary, before he or she receives specified items or services that otherwise might be paid for, that Medicare probably will not pay for them on that particular occasion and to allow the beneficiary to make an informed consumer decision whether or not to receive the items or services for which he or she may have to pay out of pocket or through other insurance. Also, the ABN allows the beneficiary to better participate in his/her own health care treatment decisions by making informed consumer decisions. If the physician or supplier expects payment for the items or services to be denied by Medicare, the physician or supplier must advise the beneficiary before items or services are furnished that, in his/her/its opinion, the beneficiary will be personally and fully responsible for payment. To be "personally and fully responsible for payment" means that the beneficiary will be liable to make payment "out-of-pocket," through other insurance coverage (e.g., employer group health plan coverage), or through Medicaid or other federal or non-federal payment source. The physician or supplier must issue notices each time, and as soon as, he/she/it makes the assessment that Medicare payment probably or certainly will not be made. If a physician or supplier fails to provide a proper ABN in situations where one is required, you may find the physician or supplier to be liable under the provisions of LOL or RR, where such provisions apply, unless the physician or supplier can show that he/she/it did not know and could not reasonably have been expected to know that Medicare would deny payment. To be acceptable, an ABN must be on the approved form CMS-R-131, must clearly identify the particular item or service, must state that the physician or supplier believes Medicare is likely (or certain) to deny payment for the particular item or service, and must give the physician's or supplier's reason(s) for his/her/its belief that Medicare is likely (or certain) to deny payment for the item or service.

1. Reason for Predicting Denial.--Statements of reasons for predicting Medicare denial of payment at a level of detail similar to those in Medicare Carriers Manual, Part 3 (MCM) §7012, Item 15.0ff., "Medical Necessity" are acceptable for ABN purposes. Simply stating "medically unnecessary" or the equivalent is not an acceptable reason, insofar as it does not at all explain why the physician or supplier believes the items or services will be denied as not reasonable and necessary. To be acceptable, the ABN must give the beneficiary a reasonable idea of why the physician or supplier is predicting the likelihood of Medicare denial, so that the beneficiary can make an informed consumer decision, whether or not to receive the service and pay for it personally. The use on the ABN-G, in the customizable "Because:" box, of lists of reasons for denial which the particular physician or supplier has found are frequently applicable, with check-off boxes or some similar method of indicating the selection of the reason(s), is an acceptable practice. For example, the three reasons included on the ABN-L form may be used, with slight modification, on the ABN-G form: "Medicare does not pay for this item or service for your condition"; "Medicare does not pay for this item or service more often than *frequency limit*"; "Medicare does not pay for services which it considers to be experimental or for research use". Listing several reasons which apply in different situations without indicating which reason is applicable in the beneficiary's particular situation generally is not an acceptable practice and such an ABN may be defective and may not protect the physician or supplier from liability. However, if more than one reason for denial could apply (e.g., exceeding a frequency limit and "same day" duplication; cases where the reason for denial could depend upon the result of a test; etc.), do not invalidate an ABN on the basis of citing more than one

reason for denial. See §7310.2.D.4.b with respect to citing the lack of a Certificate of Medical Need (CMN) as a reason for expecting a medical necessity denial.

2. Routine Notices Prohibition - Generic and Blanket Notices.--In general, the "routine" use of ABNs is not effective. By "routine" use, we mean giving ABNs to beneficiaries where there is no specific, identifiable reason to believe Medicare will not pay. Physicians and suppliers should not give ABNs to beneficiaries unless the physician or supplier has some genuine doubt that Medicare will make payment as evidenced by his/her/its stated reasons. Giving routine notices for all claims or services is not an acceptable practice. If you identify a pattern of routine notices in situations where such notices clearly are not effective, write to the physician or supplier and remind him/her/it of these standards. In general, routinely given ABNs are defective notices and will not protect the physician or supplier from liability. However, in certain circumstances, ABNs may be routinely given to beneficiaries because all or virtually all beneficiaries may be at risk of having their claims denied in those circumstances. Sections 7310.1.A.2.d.ff specify those circumstances in which ABNs may be routinely given.

a. Generic ABNs: By "generic ABNs," is meant routine ABNs to beneficiaries which do no more than state that Medicare denial of payment is possible, or that the physician never knows whether Medicare will deny payment. Such "generic ABNs" are not considered to be acceptable evidence of advance beneficiary notice. The ABN must specify the service and a genuine reason that denial by Medicare is expected. ABN standards likewise are not satisfied by a generic document that is little more than a signed statement by the beneficiary to the effect that, should Medicare deny payment for anything, the beneficiary agrees to pay for the service. "Generic ABNs" are defective notices and will not protect the physician or supplier from liability.

b. Blanket ABNs: A physician or supplier should not give an ABN to a beneficiary unless the physician or supplier has some genuine doubt regarding the likelihood of Medicare payment as evidenced by its stated reasons. Giving ABNs for all claims or items or services (viz., "blanket ABNs") is not an acceptable practice. Notice must be given to a beneficiary on the basis of a genuine judgment about the likelihood of Medicare payment for that individual's claim.

c. Signed Blank ABNs: A physician or supplier is prohibited from obtaining beneficiary signatures on blank ABNs and then completing the ABNs later. An ABN, to be effective, must be completed before delivery to the beneficiary. Hold any ABN that was blank when it was signed to be defective notice that will not protect the physician or supplier from liability.

d. Routine ABN Prohibition Exceptions: Only in the following exceptional circumstances, ABNs may be routinely given to beneficiaries and be considered to be effective notices which will protect physicians and suppliers.

i. Services Which Are Always Denied for Medical Necessity - In any case where a national coverage decision provides that a particular service is never covered, under any circumstances, as not reasonable and necessary under §1862(a)(1) of the Act (e.g., at present, all acupuncture services are denied as not reasonable and necessary), an ABN that states in the "Because:" box that: "Medicare never pays for this *item/service*" may be routinely given to beneficiaries, and no claim need be submitted to Medicare. If the beneficiary demands that a claim be submitted to Medicare, submit the claim as a demand bill in accordance with §7310.3.G.

ii. Experimental Items and Services - When any item or service which Medicare considers to be experimental (e.g., "Research Use Only" and "Investigational Use Only" laboratory tests) is to be furnished, since all such services are denied as not reasonable and necessary under §1862(a)(1) of the Act, because they are not proven safe and effective, the beneficiary may be given an ABN-G that states in the "Because:" box that: "Medicare does not pay for services which it considers to be experimental or for research use" or an ABN-L with a test listed in the third column, "Medicare does not pay for experimental or research use tests". Alternative, more specific, language with respect to Medicare coverage for clinical trials may be substituted as necessary in the ABN-G "Because:" box or as the caption for the right column of the customizable portion of the ABN-L at the user's discretion.

iii. Certain Frequency Limited Items and Services - When any item or service is to be furnished for which Medicare has established a statutory or regulatory frequency limitation on coverage, or a frequency limitation on coverage on the basis of a national coverage decision or on the basis of your local medical review policy (LMRP), because all or virtually all beneficiaries may be at risk of having their claims denied in those circumstances, the physician or supplier may routinely give ABNs to beneficiaries. In any such routine ABN-G, the physician or supplier must state the frequency limitation in the ABN-G "Because:" box (e.g., "Medicare does not pay for this item or service more often than *frequency limit*").

iv. Medical Equipment and Supplies Denied Because the Supplier Had No Supplier Number or Because the Supplier Made an Unsolicited Telephone Contact - Given that Medicare denials of payment under §1834(j)(1) of the Act on the basis of a supplier's lack of a supplier number and under ∋1834(a)(17)(B) of the Act, the prohibition on unsolicited telephone contacts, apply to all varieties of medical equipment and supplies and to all Medicare beneficiaries equally, the usual prohibition on provision of routine notices to all beneficiaries does not apply in these cases (See §7310.2.D.1 & .2).

B. Determining Whether or Not the Beneficiary is Liable.--In deciding whether the beneficiary or his/her authorized representative knew, or could reasonably have been expected to know, that payment would not be made for items or services s/he received, the beneficiary's allegation that s/he did not know, in the absence of evidence to the contrary, will be acceptable evidence for LOL purposes. However, there may be evidence that will rebut such an allegation. For example, when within the previous twelve months a beneficiary received a denial notice stating that a service was excluded from coverage, that previous denial notice, if it pertains to a similar or reasonably comparable service, would constitute evidence that the beneficiary did have knowledge of exclusion. While evidence of beneficiary knowledge generally must be based on written notice, §1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the LOL protection. If it is clear and obvious that a beneficiary in fact did know, prior to receiving a service or item, that Medicare payment for that service or item would be denied, the administrative presumption favorable to the beneficiary is rebutted. E.g., if a beneficiary admits he or she had prior knowledge that payment would be denied, no further evidence is required; the absence of a written notice is moot. The failure of any physician or supplier to furnish an ABN to a beneficiary is not sufficient to afford the beneficiary the protection of the LOL provision if you have proof that the beneficiary, nonetheless, had the requisite knowledge that payment would be denied. In any case in which you have such evidence of prior knowledge on the beneficiary's part, hold the beneficiary liable under the LOL provision. The most likely reason to find that the beneficiary knew or could reasonably have been expected to know that Medicare would not pay is where, before the item or service was furnished, the physician or supplier notified the beneficiary, by properly delivering to the beneficiary the approved form CMS-R-131, of the likelihood that Medicare would not pay for the specific service. In a case where a beneficiary received an ABN and, upon initial determination, the claim was paid as covered, that original ABN cannot be used as evidence of knowledge to hold the beneficiary liable in a later case relating to a similar or reasonably comparable service in which the same reason for denial applies, since the original ABN was belied by the favorable payment decision. In a case where RR applies, in order for the beneficiary to be held liable, it is necessary that, after being so informed, the beneficiary agreed to pay the physician or supplier for the service, personally or through other insurance, as evidenced by a signed agreement to pay. (See §7300.5 for instructions on determining liability for assigned claims for physician and supplier services for which payment is denied as "not reasonable and necessary."). Do not accept generic ABNs or blanket ABNs as effective notice to beneficiaries for either LOL or RR purposes.

C. Delivery of ABN.--Delivery of an ABN occurs when the beneficiary (or authorized representative, i.e., the person acting on the beneficiary's behalf) both has received the notice and can comprehend its contents. All notices must include an explanation written in lay language of the physician's or supplier's reason for believing the items or services will be denied payment. Do not accept an incomprehensible notice or any notice which the individual beneficiary or his/her authorized representative is incapable of understanding due to the particular circumstances (even if others may understand).

1. The physician or supplier should hand-deliver the ABN to the beneficiary or authorized representative. Delivery is the physician's or supplier's responsibility. (Consider delivery of an ABN by a physician's or supplier's staff or employees to be delivery by the physician or supplier.) If the beneficiary alleges non-receipt of notice and the physician cannot show that notice was received by the beneficiary, do not find that the beneficiary knew or could reasonably

have been expected to know that Medicare would not pay; i.e., hold the physician or supplier liable and the beneficiary not liable. The ABN must be prepared with an original and at least one copy. The physician or supplier must retain the original and give the copy to the beneficiary or authorized representative. (In a case where the physician or supplier that gives an ABN is not the entity which ultimately bills Medicare for the item or service, e.g., when a physician draws a test specimen and sends it to a laboratory for testing, the physician or supplier should give a copy of the signed ABN to the entity which ultimately bills Medicare.) The copy shall be given to the beneficiary immediately after the beneficiary signs it. Legible duplicates (carbons, etc.), fax copies, electronically scanned copies, or photocopies will suffice. This is a fraud and abuse prevention measure. If a beneficiary is not given a copy of the ABN and if the beneficiary later alleges that the ABN presented to the carrier by the physician or supplier is different in any material respect from the ABN he/she signed, give credence to the beneficiary's allegations.

2. Do not consider a telephone notice to a beneficiary, or authorized representative, to be sufficient evidence of proper notice for purposes of limiting any potential liability, unless the content of the telephone contact can be verified and is not disputed by the beneficiary. If a telephone notice was followed up immediately with a mailed notice or a personal visit at which written notice was delivered in person and the beneficiary signed the written notice accepting responsibility for payment, accept the time of the telephone notice as the time of ABN delivery.

3. Do not consider delivery of a notice to be properly done unless the beneficiary, or authorized representative, was able to comprehend the notice (i.e., they were capable of receiving notice). A comatose person, a confused person (e.g., someone who is experiencing confusion due to senility, dementia, Alzheimer's disease), a legally incompetent person, a person under great duress (for example, in a medical emergency) is not able to understand and act on his/her rights, therefore necessitating the presence of an authorized representative for purposes of notice. A person who does not read the language in which the notice is written, a person who is not able to read at all or who is functionally illiterate to read any notice, a blind person or otherwise visually impaired person who cannot see the words on the printed page, or a deaf person who cannot hear an oral notice being given by phone, or could not ask questions about the printed word without aid of a translator, is a person for whom receipt of the usual written notice in English may not constitute having received notice at all (this is not an exclusive list). This may be remedied when an authorized representative has no such barrier to receiving notice. However, in the absence of an authorized representative, the physician or supplier must take other steps to overcome the difficulty of notification. These may include providing notice in the language of the beneficiary (or authorized representative), in Braille, in extra large print, or by getting an interpreter to translate the notice, in accordance with the needs of the beneficiary or authorized representative to act in an informed manner. If the beneficiary was not capable of receiving the notice, hold that the beneficiary did not receive proper notice, hold that the beneficiary is not liable, and hold the physician or supplier liable.

4. Hold that a beneficiary did not receive proper notice in any case where you find that the physician or supplier refused to answer inquiries from a beneficiary, or authorized representative, who requested further information and/or assistance in understanding and responding to the notice, including the basis for his/her/its assessment that items or services may not be covered. In the case of a beneficiary complaint about not receiving sufficient information about the cost of a service or item for which an ABN was given, follow the guidance in §7310.3.E.1.b.vi in determining whether the physician or supplier was sufficiently responsive.

5. A patient must be notified well enough in advance of receiving a medical service so that the patient can make a rational, informed consumer decision. Last moment delivery of an ABN may be considered to be coercive, regardless of the physician's or supplier's intentions. By "last moment delivery," is meant, for example, after the beneficiary is connected to test equipment, after the beneficiary has undergone a tiring fitting, while the beneficiary is being placed in a test machine (e.g., a CAT scanner), etc., in other words, when the beneficiary is likely to feel that the service has already begun and that s/he has no choice but to continue with the service. Common sense must be applied to this criterion. It is not meant to prohibit giving an ABN to a beneficiary anytime they have entered an examination room, a draw station, a DMEPOS sales room, etc., and are ready to receive services or items. It is meant to prohibit coercion by putting the beneficiary into a position in which s/he is already "committed" to receiving the item or service before receiving notice of the likelihood of denial of payment by Medicare. In a case where a physician draws a test specimen and sends it to a laboratory for testing, and did not give the beneficiary an ABN, the

laboratory may contact the beneficiary and give him or her an ABN without violating this timely delivery rule so long as testing of the specimen has not begun. If a beneficiary alleges s/he was coerced into accepting medical items or services by receiving the ABN at the last moment, investigate the facts. If the physician or supplier clearly violated this timely delivery rule, hold that the notice was not properly delivered in advance of furnishing the item or service and that the beneficiary therefore is not liable.

D. Effect of Furnishing ABNs and Collection from Beneficiary.—

1. When ABNs are properly used by physicians and suppliers, the ABNs also protect them from liability under the several statutory provisions which limit beneficiaries' liability. A beneficiary who has been given a proper written ABN, before an item or service was furnished, giving notice of the likelihood (or certainty) that Medicare would not pay for the specific item or service and of the reason therefor and who, after being so informed, has agreed to pay the physician or supplier for the item or service, will be held liable. That is, that beneficiary will be found to have known in advance that Medicare would not pay, and the physician or supplier will be free to bill and collect the related charges from the beneficiary. A beneficiary who has been given such a proper ABN and who, after being so informed, refused to sign the ABN at all but demanded and received the item or service, may be held liable under LOL, but not under RR (see §7310.1.B, above).

2. Failure to meet the ABN standards and procedures will expose a physician or supplier to the risk of potential financial liability for denied items or services in cases where, in the absence of a proper ABN, the beneficiary would be held not to have known, nor to reasonably have been expected to have known, that his/her claims for the denied items and services he/she received were likely to be denied by Medicare. A physician or supplier held liable for such denied charges will be precluded from collecting from the beneficiary and may be required to make refunds to the beneficiary, or face possible sanctions for failure to do so. If you suspect that a physician or supplier is not furnishing ABNs with the intent to induce or coerce referrals for other items and/or services paid for by Medicare whereby anti-kickback statutes could be implicated, or if you suspect that a physician or supplier is doing so for any fraudulent, abusive, or otherwise illegal purposes, refer the case to the CMS regional office.

3. A physician or supplier who supplies a defective ABN (one which does not meet the standards in §7310ff) will not be protected from liability. A beneficiary who received a defective ABN should be held not to be liable and the physician or supplier who/which gave the defective ABN should be held liable. Certain ABN standards may vary on the basis of the particular type of denial (e.g., as not reasonable and necessary, as violating the prohibition on unsolicited telephone contacts) and on the basis of whether the claim is assigned or unassigned. Section §7310.2 provides particular standards which apply to specific types of denials.

4. When an ABN was properly executed and given timely to a beneficiary (who, if RR applies, agreed to pay in the event of denial by Medicare) and, in fact, Medicare denies payment on the related claim (whether assigned or unassigned), the physician or supplier may bill and collect from the beneficiary for that service. The physician or supplier may collect at the time of service and refund the beneficiary that amount if Medicare does pay, or he/she/it may wait to collect from the beneficiary until Medicare denies payment, unless prohibited from collecting in advance of the Medicare payment determination by State or local law. Medicare does not limit the amount which the physician or supplier, participating or nonparticipating, may collect from the beneficiary in such a situation. Medicare charge limits do not apply to either assigned or unassigned claims when collection from the beneficiary is permitted on the basis of an ABN. A beneficiary's agreement to "be personally and fully responsible for payment" means that the beneficiary agrees to pay out-of-pocket or through any other insurance that the beneficiary may have, e.g., through employer group health plan coverage or through Medicaid or other federal or non-federal payment source.

5. When an ABN was given to a beneficiary for a service for which Medicare pays in more than one part to different entities, e.g., for a radiological test with a technical component and a professional component, if the specification of the service on the ABN reasonably includes both components, that ABN, from either party, will serve as evidence of knowledge for purposes of LOL and RR. It is not necessary that both parties to the service give separate ABNs. If the beneficiary asks for a cost estimate, the estimate should include both parts of the service.

6. ABNs may not be used to shift liability to a beneficiary in the case of services or items for which full payment is bundled into other payments; that is, where the beneficiary would otherwise not be liable for payment for the service or item because bundled payment is made by Medicare. Using an ABN to collect from a beneficiary where full payment is made on a bundled basis would constitute double billing. An ABN may be used to shift liability to a beneficiary in the case of services or items for which partial payment is bundled into other payments; that is, where part of the cost is not included in the bundled payment made by Medicare.

7. HIPAA sanctions and the use of ABNs.--The Health Insurance Portability & Accountability Act of 1996 [HIPAA], §231(e)(4), adds to the Social Security Act a new §1128A(a)(1)(E) which provides for civil monetary penalties when claims are submitted "for a pattern of medical or other items or services that a person knows or should know are not medically necessary". This HIPAA sanctions provision and the ABN provisions are not related and should not be confused with one another, but also are not mutually exclusive. Concerns have been raised by the physician and supplier communities that the use of ABNs could be construed by CMS or another agency pursuing enforcement activities as documenting such a pattern of medically unnecessary care. You may assure physicians and suppliers inquiring about this matter that the use of ABNs will not run them afoul of the HIPAA sanctions. The HIPAA sanctions are meant to deal with fraudulent claims for patently unnecessary medical care. The LOL and RR ABN provisions are meant to deal with giving beneficiaries proper advance notice of the likelihood of Medicare denial of payment for medical care that may be medically unnecessary, under Medicare coverage standards, for the individual beneficiary on a specific occasion. These are entirely different provisions and should not be confused, as indicated in the Conference Report accompanying HIPAA §231 ("*the conferees intend that a penalty will be imposed on presentation of a claim that is false or fraudulent. No sanction is intended for providers who simply inform beneficiaries that a particular service is not covered by Medicare. Moreover, nothing in this section is intended to supersede the limitation on liability provisions established under Section 1879 of the Social Security Act.*"). The use of ABNs, in and of itself, is not evidence of any HIPAA sanctionable violation. At the same time, the use of an ABN does not provide any protection against the HIPAA sanctions to any physician, supplier or provider that does file a fraudulent claim. Do not hold any beneficiary who received an ABN in the case of a fraudulent claim to be properly notified under either LOL or RR; do hold the physician or supplier liable in such a case.

E. Approved Notice Language.--The OMB-approved ABNs for use with Part B items and services (viz., OMB Approval No. 0938-0566, Form No. CMS-R-131) satisfy the requirements under both LOL and RR for the physician's or supplier's advance beneficiary notice and the beneficiary's agreement to pay. The use of any other ABNs or modified ABNs may be ineffective in protecting physicians and suppliers from liability.

1. OMB Notice.--According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 5 minutes per response, including the time to review instructions, search existing data resources, and gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

2. ABN-G & ABN-L.--Forms attached to these instructions, CMS-R-131-G and CMS-R-131-L (Exhibits 1 and 2, respectively, and Spanish versions in Exhibits 1S and 2S, respectively), represent the OMB-approved ABNs for use with Part B items and services. The ABN-G and the ABN-L must be prepared with an original and at least one patient copy. The Exhibits are not replicable copies, due to formatting for these instructions. For the replicable copies of the approved forms CMS-R-131 in PDF and MSWord formats, go to the Beneficiary Notices Initiative (BNI) webpage at http://www.hcfa.gov/medicare/bni/. Physicians and suppliers must use approved ABN forms. The ABN-G may be used for all situations, including laboratory tests. The ABN-L may be used for physician-ordered laboratory tests. Laboratories are permitted to reproduce the ABN on the back of their laboratory test requisition forms. ABNs may be produced using self-carboning paper and other methods of producing copies, including photocopying, printing, and electronic generation.

3. User-Customizable Sections.--Physicians and suppliers are permitted to

customize the header, the "Items or Services" and "Because" box area on the HCFA-R-131-G, and the header and the reasons and tests 3-column box area on the HCFA-R-131-L form. The box containing three columns for laboratory tests and reasons for expecting denial on the ABN-L is customizable by the physician or supplier, except that the captions (reasons) for the left and center columns may not be revised while the right column (experimental and research use exclusion) may be revised or deleted at the discretion of the physician or supplier. Do not invalidate an ABN solely on the basis that the physician or supplier included in a customizable area some item(s) of information (e.g., information about the ABN's implications for the beneficiary's other insurers) which is/are not explicitly required by these instructions. The specified box areas are customizable and are scalable (that is, they may be lengthened). The ABN is designed as a letter-size form; nevertheless, it may be expanded to a legal size form by a user, to allow increasing the size of the customizable box areas, to suit the physician's or supplier's particular needs. In any case, the ABN must be only one page in length and may be modified only in the specified user-customizable sections. The standard sections of the forms (those sections which are not specified as user-customizable) may not be modified in any respect; they must be identical to the replicable PDF forms files at the website address provided in subparagraph 2 above. The use of improperly modified ABNs may be ineffective in protecting physicians and suppliers from liability.

F. Definition of Authorized Representative.-- An authorized representative is a person who is acting on the beneficiary's behalf and in the beneficiary's best interests, and who does not have a conflict of interests with the beneficiary, when the beneficiary is temporarily or permanently unable to act for himself or herself. If you receive an allegation that the person (not the beneficiary) who signed an ABN was not a properly authorized representative, use the following guidance in deciding if the beneficiary can be held liable. Ultimately, if a situation arises in which a beneficiary simply cannot receive an ABN and notice cannot be given to an authorized representative, the beneficiary is protected by not having received an ABN. A physician's or supplier's inability to give notice to a beneficiary directly or through an authorized representative does not allow the physician or supplier to shift liability to the beneficiary.

1. The first consideration with respect to an "authorized representative" is the most important. An individual authorized under State law to make health care decisions, e.g., a legally appointed representative or guardian of the beneficiary (if, for example, the beneficiary has been legally declared incompetent by a court), or an individual exercising explicit legal authority on the beneficiary's behalf (e.g., in accordance with a properly executed "durable medical power of attorney" statement or similar document), may be the authorized representative of the beneficiary with respect to receiving ABNs.

2. The second consideration with respect to an authorized representative is that s/he should have the beneficiary's best interests at heart. That is, the authorized representative should be reasonably expected to act in a manner which is protective of the rights of the beneficiary, and is protective of the beneficiary himself or herself. In the absence of some more compelling consideration, the order of priority of authorized representatives should be: the spouse, unless legally separated; an adult child; a parent; an adult sibling; and, if none of these are available, a close friend (defined as "an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, and who is reasonably available").

3. The third consideration for an authorized representative is that s/he should have no relevant conflict of interests with the beneficiary. That is, even though a particular individual may sincerely like a beneficiary and wish him or her well, if that individual is an employee of a physician or supplier that is notifying the beneficiary about the likelihood of noncoverage by Medicare and has a competing/conflicting financial interest (such as shifting liability for a service to the beneficiary), that individual is not qualified to be an authorized representative.

4. Another possible consideration with respect to an authorized representative is whether the person is someone (typically, a family member or close friend) whom the beneficiary has indicated may act for him or her, but who has not been named in any legally binding document conveying such a role to that person. Presently, a majority of States have health care consent statutes providing for health care decision-making by surrogates on behalf of patients who lack advance directives and guardians. In such States, reliance upon individuals appointed / designated under such statutes to act as authorized representatives may be necessary. In this last case, such a person may well be a more appropriate authorized representative (in terms of having the best

interests of the beneficiary at heart) than some other person with some official standing short of actually being legally appointed representative or guardian of the beneficiary (e.g., an ombudsman).

5. Finally, another possible consideration with respect to an authorized representative is a disinterested third party. That is, while a beneficiary who is temporarily unable to act for himself or herself should have an authorized representative who can make decisions and receive notices for him or her, it is entirely possible that, in any particular case, especially where the beneficiary's inability to act has arisen suddenly (e.g., a medical emergency, a traumatic accident, an emotionally traumatic incident, disabling drug interaction, stroke, etc.), there may be no one who can be genuinely considered to be the beneficiary's choice as his or her authorized representative. In such a case, recourse may be made to a disinterested third party, such as a public guardianship agency, taking care to avoid any conflicts of interest.

7310.2 Special Rules

A. Exception for Repetitive Notices.--A single ABN covering an extended course of treatment is acceptable provided the ABN identifies all items and services for which the physician or supplier believes Medicare will not pay. If, as the extended course of treatment progresses, additional items or services are to be furnished for which the physician or supplier believes Medicare will not pay, the physician or supplier must separately notify the patient in writing (i.e., give the beneficiary another ABN) that Medicare is not likely to pay for the additional items or services and obtain the beneficiary's signature on the ABN. Items or services (e.g., laboratory tests) provided on a regularly scheduled basis under a "standing order" may be considered, for these beneficiary notice purposes only, as an extended course of treatment; and a single ABN may suffice (e.g., for all the tests furnished the beneficiary which are contemplated by that order), as described above, with a new ABN being required only when additional items or services, which are not specified by the initial course of treatment ABN and for which noncoverage is expected, are to be furnished to the beneficiary. When an ABN is to be given for a "standing order" the physician or supplier must specify in the "Items or Services:" box of the ABN-G, or in the appropriate column of the customizable box beginning "Medicare probably will not pay…" on the ABN-L, the pertinent facts (e.g., frequency and duration) of the standing order (see §7310.3.E.1.b.v.). One year is the limit for use of a single ABN for an extended course of treatment; if the course of treatment extends beyond one year, a new ABN is required for the remainder of the course of treatment. An ABN, once signed by the beneficiary, may not be modified or revised. When a beneficiary must be notified of new information, a new ABN must be given.

B. Guidelines for Situations Where the Beneficiary is in a Medical Emergency or Is Otherwise Under Great Duress.-- An ABN-G or ABN-L should not be obtained from a beneficiary in a medical emergency or otherwise under great duress (i.e., when circumstances are compelling and coercive) since that individual cannot be expected to make a reasoned informed consumer decision. In genuine emergencies, the beneficiary/victim and his or her family/friends (authorized representative) are under great duress, by the emergency circumstances, to sign anything in order to obtain help. On the other hand, there is a risk that beneficiaries might actually forego needed emergency services if faced with a financial burden which they believe they cannot bear. A requirement for delivery of a notice is that the beneficiary, or authorized representative, must be able to comprehend the notice, i.e., they must be capable of receiving notice (see §7310.1.C.3). A person under great duress is not able to understand and act on his or her rights. If the beneficiary is not capable of receiving the notice, then the beneficiary has not received proper notice and cannot be held liable where the LOL or RR provisions apply, and the physician or supplier may be held liable.

1. EMTALA Situations.--An ABN should not be given to a beneficiary in any case in which EMTALA (§1876 of the Act) applies, until the hospital has met its obligations under EMTALA, which includes completion of a medical screening examination (MSE) to determine the presence or absence of an emergency medical condition, or until an emergency medical condition has been stabilized. CMS published this policy in the November 10, 1999 OIG/HCFA Special Advisory Bulletin on the Patient Anti-Dumping Statute: "A hospital would violate the patient anti-dumping statute if it delayed a medical screening examination or necessary stabilizing treatment in order to prepare an ABN and obtain a beneficiary signature. The best practice would be for a hospital not to give financial responsibility forms or notices to an individual, or otherwise attempt to obtain the individual's agreement to pay for services before the individual is stabilized. This is

because the circumstances surrounding the need for such services, and the individual's limited information about his or her medical condition, may not permit an individual to make a rational, informed consumer decision." This policy applies in any case in which EMTALA applies, not only to EMTALA cases seen in emergency rooms (ERs). Giving ABNs to beneficiaries under great duress is not permitted, regardless of the particular treatment setting or location. Even when a beneficiary does not appear to have a life threatening condition, rather, he or she is seeking primary care services at an ER, an ABN should not be given to the beneficiary in any case in which EMTALA applies until the hospital has met its obligations under EMTALA. An ABN that is otherwise appropriate may be given to a Medicare beneficiary who is seen in the ER after completion of an MSE, but an ABN should not be given unless there is a genuine reason to expect that Medicare will deny payment for the services because giving routine "blanket" ABNs to beneficiaries is not permitted (see §7310.1.A.2.b.). There always must be a reason for expecting that Medicare will deny payment for the services furnished to the individual beneficiary on a specific occasion, and that reason must appear on the ABN. EMTALA does not prohibit asking payment questions entirely, rather, only doing so before screening/stabilization. After screening/stabilization, EMTALA no longer applies and ABNs may be given, when otherwise appropriate, to beneficiaries who come to emergency care settings after they have received a medical screening examination and are stabilized.

2. Other Situations.--A physician or supplier may not shift liability to a beneficiary under great duress by giving an ABN to the beneficiary. ABNs given to any individual who is under great duress cannot be considered to be proper notice. It is inconsistent with the purpose of advance beneficiary notice, which is to facilitate an informed consumer decision by a beneficiary whether or not to receive an item or service and pay for it out-of-pocket, to attempt to obtain beneficiaries' signatures on ABNs during medical emergencies and other compelling, coercive circumstances where a rational, informed consumer decision cannot reasonably be made. For that reason, physicians and suppliers may not use ABNs to shift financial liability to beneficiaries in emergency care situations. Ambulance companies may not give ABN-Gs to beneficiaries at all since: (i.) all routine ambulance service denials would be exclusions under §1861(s)(7) of the Act, which does not trigger LOL; and (ii) any "medical necessity" denial situation which could arise would be in emergency circumstances in which giving an ABN-G would be improper. Skilled nursing facilities may not give ABN-Gs in the case of "middle-of-the-night" emergencies or in any other emergency circumstances, since the beneficiary clearly cannot make an informed consumer decision (see §7310.2.G). Consider any ABN-G or ABN-L given in any kind of coercive circumstances, including medical emergencies, to be defective. In all such coercive situations, find that the beneficiary did not know and could not reasonably have been expected to know that Medicare would not make payment. Determine the physician's or supplier's liability by the appropriate knowledge standards which are used in cases where ABNs are not given and beneficiary agreements to pay are not obtained (see §§ 7300.5.B, 7330.D.1, and 7340.5). This policy regarding duress applies in any case in which a beneficiary is under great duress and cannot make an informed consumer decision. This is the basis for the "last moment delivery" policy that a beneficiary must be notified well enough in advance of receiving a medical service so that the beneficiary can make a rational, informed consumer decision. In any case of such "last moment delivery" of an ABN, the delivery may not be considered timely and the beneficiary may not be held liable (see §7310.1.C.5 regarding "last moment delivery" of the ABN).

C. ABNs for Claims Affected by the Physicians' Services Refund Requirement.--Under §1842(1) of the Act, the prohibition against billing for unassigned physician services which are denied on the basis of §1862(a)(1) of the Act as not reasonable and necessary, the physicians' services Refund Requirement provision, a refund is required under certain circumstances, unless a proper ABN-G was given the beneficiary and the beneficiary agreed to pay. (See §7330 for instructions on determining situations where a refund under §1842(1) of the Act is required.)

D. ABNs for Claims Affected by the Medical Equipment and Supplies Refund Requirement.-- Under §1834(a)(18)(A)(ii), a refund is not required of the supplier if, before the medical equipment or supplies were furnished, the beneficiary was informed by the supplier that Medicare would not pay for the specific item or service and, after receiving such an advance beneficiary notice, the beneficiary agreed to pay for the item or service. The Refund Requirement provisions of §1834(a)(18) are incorporated by reference in §§ 1834(j)(4) and 1879(h), which are also limits on beneficiaries' liability for denied claims (unassigned and assigned, respectively) for medical equipment and supplies. (See §7340 for the medical equipment and supplies Refund Requirement instructions.)

1. Using ABNs for Medical Equipment and Supplies Claims When Denials Under §1834(a)(17)(B) (Prohibition Against Unsolicited Telephone Contacts) Are Expected.--To qualify for waiver of the Refund Requirements under §1834(a)(18) or §1879(h)(3) of the Act (unassigned and assigned claims, respectively), an ABN must clearly identify the particular item or service and state that the supplier expects that Medicare will deny payment for that particular medical equipment or supplies because the supplier violated the prohibition on unsolicited telephone contacts. The supplier must obtain a signed ABN before furnishing the item to the beneficiary. Since it is the unsolicited telephone contact which is prohibited by law, giving advance beneficiary notice by telephone does not qualify as notice and is not permissible. The telephone notice process described in §7310.1.C.2. may not be used in this case. Do not accept any telephone ABN as effective notice to the beneficiary. Since giving or mailing a written ABN and obtaining the beneficiary's agreement to pay before telephoning is equivalent to obtaining the beneficiary's written permission for the supplier to telephone under §1834(a)(17)(A)(i) of the Act, a supplier has little to gain from using the ABN process instead of simply seeking the beneficiary's written permission to contact him or her. If a supplier does use a written ABN prior to calling, the beneficiary's agreement to pay is essential under the Refund Requirements in order for the supplier to collect from the beneficiary. Medicare denial of payment because of the prohibition on unsolicited telephone contacts applies to all varieties of medical equipment and supplies and to all Medicare beneficiaries equally. Therefore, the usual restriction on routine notices to all beneficiaries does not apply in this case. (See §7310.1.A.2.d.iv. for exception to prohibition on routine ABNs.)

2. ABNs for Medical Equipment and Supplies Claims Denied Under §1834(j)(1) Because the Supplier Did Not Meet Supplier Number Requirements.—

a. To qualify for waiver of the Refund Requirements under §1834(j)(4)(A) and §1879(h)(1) of the Act (unassigned and assigned claims, respectively) for medical equipment and supplies for which payment will be denied due to failure to meet supplier number requirements under §1834(j)(1) of the Act, the ABN must state that Medicare will deny payment for any medical equipment or supplies because the supplier does not have a supplier number. The ABN must convey to the beneficiary the certainty of denial, so that the beneficiary can make an informed consumer decision whether to receive the medical equipment or supplies and pay for it out of pocket. The following is acceptable language for the ABN-G "Because:" box: "Medicare will pay for items furnished to you by a supplier of medical equipment and supplies only if the supplier has a Medicare supplier number. Payment for such items furnished to you by a supplier which does not have a supplier number is prohibited under the Medicare law. We do not have a Medicare supplier number, therefore, Medicare will not pay for any medical equipment and supplies which we furnish to you." It is particularly important that the beneficiary's signed agreement to pay should be dated by the beneficiary because, in this type of denial, any proper written advance notice with the beneficiary's signed agreement to pay shall be effective for any medical equipment or supplies purchased or rented from the same supplier within the one year following the date of the beneficiary's signed agreement to pay. This exception relieves the supplier, which has duly notified a beneficiary of its lack of a supplier number and the fact that Medicare will not pay, from the necessity of obtaining a signed agreement from the beneficiary every time the beneficiary does business with the supplier.

b. Exception to ABN Requirement: A supplier which can show that it did not know and could not reasonably have been expected to know that a customer was a Medicare beneficiary, or that a customer was making a purchase for a Medicare beneficiary, can seek protection under the LOL provision, §1879 of the Act, or, in the case of unassigned claims, under the applicable RR provision, §1834(j)(4) of the Act. If the supplier can show that a person who is not a Medicare beneficiary made a purchase on behalf of a person who is a Medicare beneficiary and did not apprise the supplier of the fact that the purchase was being made on behalf of a Medicare beneficiary, the supplier may be protected. If the supplier can show that a Medicare beneficiary who made a purchase did not identify himself or herself as a Medicare beneficiary and that the person's age or appearance was such that the supplier could not reasonably have been expected to know or surmise that the person was a Medicare beneficiary, the supplier may be protected. These protections are meant for an honest supplier in the rare case where a Medicare beneficiary who is relatively youthful, healthy and able in appearance does not identify himself or herself as a beneficiary and the supplier understandably does not surmise that he or she might be a Medicare beneficiary. If the beneficiary disputes the supplier's allegation and conclusive proof of the allegation is not presented, the supplier's allegation may not be accepted. If the involved Medicare

beneficiary is found to be obviously aged and/or disabled, such that any adult person working for a supplier would reasonably surmise that he or she could be a Medicare beneficiary, the supplier's allegation may not be accepted. If the beneficiary purchased an item which would strongly suggest to any reasonable adult person working for a supplier that the beneficiary is aged and/or disabled, the supplier's allegation may not be accepted. If a supplier can show that a customer, who is a Medicare beneficiary or was making a purchase for a Medicare beneficiary and did not identify him/herself accordingly to the supplier, was on notice of the necessity to so self-identify, the beneficiary may be held liable under §1879 or §1834(j)(4) of the Act, in which case the supplier could collect from the beneficiary. Given the possible difficulty of showing conclusively that it did not know and could not reasonably have been expected to know that a customer was a Medicare beneficiary, or that a customer was making a purchase for a Medicare beneficiary, a supplier would be well advised to consider using signage, giving public notice alerting customers that they need to inform the supplier if they are a Medicare beneficiary or are making a purchase for a Medicare beneficiary. If a supplier which does not have a supplier number provides adequate public notice to a Medicare beneficiary before medical equipment or supplies are furnished, e.g., by means of clearly visible signs, and if the adequacy of such public notice is not disputed by the beneficiary, the supplier can qualify for waiver of the Refund Requirements. Such public notices must be such that Medicare beneficiaries (1) are virtually certain to see them before purchasing or renting Medicare-covered medical equipment or supplies from the supplier (that is, they are posted in places where they are most likely to be seen by the target audience), and (2) may reasonably be expected to be able to read them and to understand them. Therefore, such public notices must be readily visible, in easily readable plain language, in large print, and would have to be provided in the language(s) commonly used in the locality. The following is acceptable language for the public notice: "Notice to Medicare Beneficiaries. Medicare will pay for medical equipment and supplies only if a supplier has a Medicare supplier number. We do not have a Medicare supplier number. Medicare will not pay for any medical equipment and supplies we sell or rent to you. You will be personally and fully responsible for payment." Do not hold any beneficiary who cannot read any such public notice of a supplier to be properly notified in advance by the supplier that Medicare will not pay. If a supplier alleges that it provided adequate public notice to Medicare beneficiaries but a beneficiary disputes the allegation, in the absence of conclusive evidence in favor of the supplier, do not hold the beneficiary to be properly notified in advance by the supplier that Medicare will not pay; hold the supplier liable. The RR provision that the beneficiary must agree to pay for the item or service makes the use of signage without an ABN a risk for the supplier. It would be in a supplier's best interest to issue ABNs advising beneficiaries that they will have to pay for supplies and to post public notices in its store(s) which inform beneficiaries of the fact that it is not a Medicare enrolled supplier and that claims for supplies purchased from that supplier will be denied payment by Medicare.

c. Medicare denial of payment on the basis of a supplier's lack of a supplier number applies to all varieties of medical equipment and supplies and to all Medicare beneficiaries equally. Therefore, the usual restriction on routine notices to all beneficiaries does not apply in this case. (See §7310.1.A.2.d.iv for exception to prohibition on routine ABNs.) Given the potential for beneficiary disputes over suppliers' public notice efforts to result in supplier liability, all suppliers which do not have supplier numbers would be very well advised to provide the standard written ABN to all Medicare beneficiaries, obtaining their signed agreement. The use of written notices in conjunction with public notices will provide maximum protection to suppliers as well as more surely providing proper advance notice to beneficiaries so that they can make informed consumer decisions.

3. ABNs for Medical Equipment and Supplies Claims Denied in Advance Under §1834(a)(15) - Prior Authorization Procedures.--To qualify for waiver of the Refund Requirements under §1834(j)(4)(B) and §1879(h)(2) of the Act (unassigned and assigned claims, respectively) for medical equipment and supplies for which payment is denied in advance under §1834(a)(15) of the Act, the ABN-G must clearly identify the particular item of medical equipment and supplies and must state in the "Because:" box either: "Medicare has denied payment in advance and we expect that Medicare will continue to deny payment." or "Medicare requires that we request an advance determination of coverage of this medical equipment and/or supplies. We have not requested an advance determination, so we expect that Medicare will deny payment.", as applicable. Denial of payment in advance under §1834(a)(15) refers both to cases in which the supplier requested an advance determination and you determined that the item would not be covered, and to cases in which the supplier failed to request an advance determination when such a request is mandatory (see §7340.5.B.).

4. ABNs for Unassigned Claims for Medical Equipment and Supplies Which Are Denied on the Basis of §1862(a)(1) of the Act, as Not Reasonable and Necessary.—

a. To qualify for waiver of the Refund Requirements under §1834(j)(4)(C) of the Act, the ABN-G must clearly identify the particular item of medical equipment and supplies for which the supplier believes that Medicare will deny payment and must give in the "Because:" box the supplier's reason(s) for its belief that Medicare will deny payment.

b. The lack of a Certificate of Medical Necessity (CMN) for a particular DME item is an acceptable reason for expecting denial of a claim and would satisfy the requirements of what would constitute an acceptable notice; e.g., "Medicare cannot pay for this item because the doctor did not complete the certificate of medical need." Where a physician has been asked to render a CMN and refuses to do so, then the failure of a supplier to obtain a CMN would result in the claim being denied for medical necessity purposes. Giving an ABN is neither the first nor the only supplier action called for in this situation. While a supplier may ultimately give an ABN to a beneficiary, that is by no means the only responsibility of the supplier in this situation. The supplier first must make a good faith effort to obtain a CMN from the physician on a timely basis; this responsibility must not be simply shifted to beneficiaries through routinely giving ABNs. If the supplier's genuine efforts to obtain a CMN fail, then the supplier advising the beneficiary, in conjunction with giving an ABN, to request his or her physician to provide a CMN, would be a prudent practice.

E. ABN Standards for Partial Denials on the Basis of Medical Necessity.--Physicians and suppliers may give an ABN when they expect you to reduce the level of payment on the basis of §1862(a)(1), that is, when they expect a partial denial of a more extensive service or item on the basis that it is not reasonable and necessary under §1862(a)(1), even though you pay for a less extensive service or item. A case in which you reduce the level of payment because a component of the service or item is in excess of the beneficiary's medical needs is a medical necessity partial denial of that unnecessary component of the covered item or service. By "excess component" is meant an item, feature, or service, and/or the extent of, number of, duration of, or expense for an item, feature, or service, which is in addition to, or is more extensive and/or more expensive than, the item or service which is reasonable and necessary under Medicare's coverage requirements. The ABN given in the case of an expected partial denial must clearly identify, in the "Items or Services:" box, the excess component(s) of the item or service for which denial is expected (it is the part of the item or service that is expected to be denied that is the subject of the ABN, not the part that is expected to be paid) and must state in the "Because:" box the reason that Medicare is expected to deny payment for the specified excess component(s). Do not accept charge increases on the basis of purported premium quality services as "excess components" since that would constitute circumvention of payment limits and applicable charging limits (e.g., limiting charges in the case of unassigned claims for physicians' services and fee schedule amounts in the case of assigned claims). For example, a physician cannot charge extra amounts over Medicare payment limits for a service on the basis that his or her service is a "higher quality" than the same service furnished by other physicians and shift liability for that extra amount to a beneficiary who receives that service by obtaining the beneficiary's agreement to pay on an ABN. The "excess component" definition for partial denials, with respect to an item, feature, or service that is "more expensive" refers to increased charges attributable to furnishing something that is clearly more extensive, that is, more in number, more frequent, for a longer period of time, or with added features. It does not suffice to claim that an item or service is "better" or "higher quality."

F. ABN Standards for Upgraded DMEPOS.-- When upgraded DMEPOS is to be furnished and the physician or supplier expects you to reduce the level of payment based on a medical necessity partial denial of coverage for additional expenses attributable to the upgrade, an ABN-G should first be delivered to the beneficiary and the signature of the beneficiary, agreeing to be personally and fully responsible for payment, should be obtained. The ABN should specify, in the "Items or Services:" box, the excess component(s) for which denial is expected (it is the upgrade features that are expected to be denied that are the subject of the ABN, not the standard items/services for which payment is expected) and must state in the "Because:" box the reason that Medicare is expected to deny payment for the specified excess component(s) related to the upgrade. Statements of reasons for predicting Medicare denial of payment at a level of detail similar to those in Medicare Carriers Manual, Part 3 (MCM) §7012, Item 15.0ff., "Medical Necessity" are acceptable for ABN purposes, for example, "Your condition does not support the need for the

special features of this equipment." An "upgrade," for purposes of these instructions, is synonymous with an "excess component," as defined in §7310.2.E. For example, a deluxe or aesthetic feature of an upgraded item of medical equipment is an "excess component." ABNs may not be used for substitution of a dissimilar item or service that is not both medically appropriate for the beneficiary's medical condition and consistent with the attending physician's original order for the item or service, e.g., ABNs may not be used for substitution of a wheelchair when a cane was prescribed, nor for a hospital bed when a wheelchair was prescribed. Any cost estimate provided on the ABN-G must relate to the extra expense for the upgrade features, over and above the Medicare allowable amount for the standard item or service, not to the total cost of the item or service.

G. ABN Standards for Services in Skilled Nursing Facilities.--Skilled nursing facilities (SNFs) may not give ABNs to beneficiaries in the case of "middle-of-the-night" emergencies, since the beneficiary is under duress and clearly cannot make an informed consumer decision. Authorized representatives for beneficiaries resident in SNFs are unlikely to be readily available for such emergencies and, depending upon the closeness of their personal relationship with the beneficiary, may also be under duress in a medical emergency. SNF staff may not sign ABNs for beneficiaries as their authorized representatives. If there is an item or service which may predictably be needed in such emergency situations, the SNF, or the physician or supplier that will furnish such an item or service to a beneficiary in the SNF, can give an ABN for a standing order for that item or service to the beneficiary, or to the authorized representative as appropriate, well in advance, when she or he is not in an emergency situation, in order to authorize furnishing the item or service when the need does arise (see §7310.2.A regarding standing orders). The effectiveness of such an ABN cannot extend beyond one year; at the end of a year, another ABN would need to be given. This procedure may be used for other, non-emergency items and services which are foreseeable, e.g., an ABN for a standing order for laboratory tests when the collection of samples may be at a time when the authorized representative is unlikely to be available, or the beneficiary may be at reduced capacity (e.g., the beneficiary will be awakened during the night). SNFs need to plan for the provision of ABNs given the particular needs of their resident population. A SNF which does not so plan ahead may find itself in a situation where delivery of an ABN is not possible, in which case liability cannot be shifted to the beneficiary.

H. ABN Standards for Items and Services for Which ABNs Are Not Required.--Physicians and suppliers need use ABNs only when Medicare is expected (or certain) to deny payment on the basis of one of the following statutory exclusions: §1862(a)(1) & (9); §1834(a)(17)(B); §1834(j)(1); and §1834(a)(15). ABNs are not required in the case of statutorily excluded items and services not listed above. Examples of exclusions for which ABNs are not required include, but are not limited to: personal comfort items; routine physicals and most tests for screening; most shots (vaccinations); routine eye care, eyeglasses and examinations; hearing aids and hearing examinations; cosmetic surgery; most outpatient prescription drugs; orthopedic shoes and foot supports (orthotics); dental care and dentures (in most cases); routine foot care and flat foot care; services under a physician's private contract; services paid for by a governmental entity that is not Medicare; health care received outside of the USA; services by immediate relatives; services required as a result of war; services for which there is no legal obligation to pay; home health services furnished under a plan of care, if the agency does not submit the claim; items and services excluded under the Assisted Suicide Funding Restriction Act of 1997; items or services furnished in a competitive acquisition area by any entity that does not have a contract with the Department of Health and Human Services (except in a case of urgent need); physicians' services performed by a physician assistant, midwife, psychologist, or nurse anesthetist, when furnished to an inpatient, unless they are furnished under arrangements by the hospital; items and services furnished to an individual who is a resident of a skilled nursing facility or of a part of a facility that includes a skilled nursing facility, unless they are furnished under arrangements by the skilled nursing facility; services of an assistant at surgery without prior approval from the peer review organization; and outpatient occupational and physical therapy services furnished incident to a physician's services (see §1862(a) of the Act for a more complete listing). ABNs also are not required when Medicare is expected to deny payment for an item or service which may be a Medicare benefit but for which the coverage requirements (not listed above) are not met, e.g., when a service is covered only in a qualifying setting and the service in question was not provided in such a qualifying setting. In situations in which ABNs are not required, the lack of an ABN, by itself, will not prevent a physician or supplier from collecting from a beneficiary. In situations in which ABNs are not required, physicians and suppliers are neither required to nor prohibited from voluntarily giving some sort of notice to beneficiaries anyway, as a prudent customer service, however, since standard ABN forms include language asking for a claim to be submitted to Medicare, physicians and

suppliers who wish to give notice in these situations should not use the CMS-R-131 ABN forms.

7310.3 The Proper Use of the ABN (CMS-R-131).--

A. When An ABN Should Be Given.--

1. Whether an ABN should be given in a particular instance depends on the physician's or supplier's expectation of Medicare payment or denial.

a. If the physician or supplier expects Medicare to pay, an ABN should not be given.

b. If the physician or supplier "never knows whether or not Medicare will pay," an ABN should not be given.

c. If the physician or supplier expects Medicare to deny payment, the next question is: "On what basis is denial expected?"

i. If the item or service is not a Medicare benefit (e.g., routine physical and tests in the absence of signs and symptoms, routine foot care, dental care), neither the ABN-G nor the ABN-L should be given.

ii. If Medicare is expected to deny payment for an item or service which is a Medicare benefit because it does not meet a technical benefit requirement (e.g., an ambulance service denied due to an unapproved destination, diabetic care shoes not prescribed by a podiatrist or other qualified physician), neither the ABN-G nor the ABN-L should be given.

iii. If Medicare is expected to deny payment (entirely or in part) for the item or service because it is not reasonable and necessary under Medicare program standards (viz., "medical necessity denials" under §1862(a)(1) of the Act), the ABN-G or the ABN-L, as appropriate, should be given (this is applicable to all assigned Part B items and services, and to unassigned physicians' services and medical equipment and supplies). Certain screening tests (mammography, pap smear, pelvic exam, glaucoma, prostate cancer, colorectal cancer) have frequency limits under §1862(a)(1) of the Act, therefore, LOL applies and ABNs should be given when Medicare denial of payment for frequency is expected for any of these tests.

iv. If Medicare is expected to deny payment for medical equipment and supplies because it is not covered: (i) under §1834(a)(17)(B), violation of the prohibition on unsolicited telephone contacts; (ii) under §1834(j)(1), supplier number requirements not met; or (iii) under §1834(a)(15), failure to obtain advance determination of coverage, the ABN-G should be given (this is applicable to both assigned and unassigned medical equipment and supplies).

2. Do not find a physician or supplier to have violated the prohibition on routine ABNs solely on the basis of the number of ABNs which the physician or supplier gives to beneficiaries, when those ABNs are justified by the physician or supplier having a genuine reason to give an ABN. Some physicians or suppliers (e.g., a physician furnishing acupuncture services) may give ABNs to most or all of their Medicare patients without violating the routine ABNs prohibition.

B. To Whom An ABN May Be Given.-- An ABN may be given to a Medicare beneficiary or to the beneficiary's authorized representative, that is, to a person who is acting on the beneficiary's behalf when the beneficiary is temporarily or permanently unable to act for himself or herself. (See the definition of an authorized representative for ABN purposes in §7310.1.F).

C. How An ABN May Be Given.--Delivery of an ABN occurs when the beneficiary (or authorized representative, i.e., the person acting on the beneficiary's behalf) both has received the notice and can comprehend its contents. An incomprehensible notice, or a notice which the individual beneficiary or his/her authorized representative is incapable of understanding due to the particular circumstances (even if others may understand), cannot be used to fulfill notice requirements. (See the applicable standards for delivery of an ABN in §7310.1.C).

D. Choosing The Form To Use.-- Physicians and suppliers must use the OMB-approved

ABNs (ABN-G and ABN-L) for use with Part B items and services. The ABN-G may be used for all situations, including laboratory tests, by all physicians and suppliers. The ABN-L may be used for laboratory tests, by any person or entity furnishing laboratory tests.

E. Filling Out The Forms.--

1. Form Instructions for ABN-G and ABN-L --

a. Format of Insertions on ABN.-- The physician or supplier must ensure that the readability of the ABN facilitates beneficiary understanding. No insertion into the blanks and boxes of the ABN, if typed or printed, should use italics nor any font that is difficult to read. An Arial or Arial Narrow font, or a similarly readable font, in the font size range of 10 point to 12 point, is recommended. Black or dark blue ink on a white background is strongly recommended. A visually high-contrast combination of dark ink on a pale background is required. Low-contrast combinations and block shading are prohibited. If insertions are handwritten, they must be legible. In all cases, both the originals and copies of ABNs must be legible and high-contrast. When Spanish language ABNs are used, the physician or supplier should make insertions on the form in Spanish to the best of their ability; where that is impossible, the physician or supplier needs to take other steps as necessary to ensure that the beneficiary understands the notice.

b. Filling in the Form.--

i. The ABN's header should have the identifying information of the billing entity. If the billing entity is a group practice, then the group practice may have its identifying information in the header. It may be prudent for each member of a group practice to also include their name in the header, but it is not required. A laboratory should put its own identifying information in the header where a client physician is delivering the ABN form to a beneficiary on behalf of the laboratory. ABNs included on laboratory requisition forms should have the identifying information of the laboratory in the header, not the client physician's information, even when stocks of the ABNs are provided to client physicians for their use in ordering tests. The physician or supplier puts his/her/its name, address and telephone number at the top of the notice header; and may elect to include his/her/its logo (if any). Within these general rules, a notice header is customizable by the physician or supplier.

ii. "Patient name" Line-- The physician or supplier enters the name of the patient, not substituting the name of an authorized representative.

iii. "Medicare # (HICN) Line-- The physician or supplier enters the patient's Medicare health insurance claim number. Do not invalidate an ABN solely for the lack of a Medicare HICN unless the beneficiary recipient of an ABN alleges that the ABN was signed by someone else of the same name and you cannot resolve the matter with certainty.

iv. ABN-G Customizable Boxes--In the section of the ABN-G beginning "We expect that Medicare will not pay for the item(s) or service(s) …", in the first box "Items or Services:", the physician or supplier specifies the health care items or services for which he/she/it expects Medicare will not pay. The items or services at issue must be described in sufficient detail so that the patient can understand what items or services may not be furnished. HCPCS codes by themselves are not acceptable as descriptions. The use on the ABN of a list of the items and/or services which the particular physician or supplier frequently furnishes, with check-off boxes or some similar method of identifying the particular items or services for which denial is predicted, is an acceptable practice. Listing several items and/or services without indicating which is/are applicable in the beneficiary's particular situation is not an acceptable practice and such an ABN is defective and will not protect the physician or supplier from liability. In the second box "Because:", the physician or supplier gives the reason why he/she/it expects Medicare to deny payment. The reason(s) must be sufficiently specific to allow the patient to understand the basis for the expectation that Medicare will deny payment. The physician or supplier may customize these two boxes for his/her/its own use.

v. ABN-L Customizable Boxes--In the section of the ABN-L beginning "Medicare probably will not pay…", the physician or supplier specifies the laboratory tests for which he/she/it expects Medicare will not pay in the customizable boxes. The laboratory tests at issue must be described in sufficient detail so that the patient can understand what laboratory

tests may not be furnished. The use of standard laboratory test descriptions is permitted. HCPCS codes by themselves are not acceptable as descriptions. ABN-L has been designed with three columns with the specific reasons for expected denial captioning these columns. The physician or supplier enters or preprints laboratory tests in these three columns; the use of check off boxes is permitted. This format allows the physician or supplier to customize the ABN-L with a preprinted list of tests linked to the captioned reasons for denial. The boxes containing three columns for laboratory tests and reasons for expecting denial on the ABN-L is customizable by the physician or supplier, except that the captions (reasons) for the left and center columns may not be revised while the right column (experimental and research use exclusion) may be revised or deleted at the discretion of the user. Use of the right column to specify the frequency and/or duration of a standing order is permissible (see §7310.2.A). Use of a fourth category, "Other:" is permissible.

vi. "Estimated Cost" Line--The physician or supplier may provide the patient with an estimated cost of the items and/or services. The patient may ask about the cost and jot down an amount in this space. The physician or supplier should respond to such inquiries to the best of his/her/its ability. The lack of an amount on this line, or an amount which is different from the final actual cost, does not invalidate the ABN; an ABN should not be considered to be defective on that basis. In the case of an ABN which includes multiple items and/or services, it is permissible for the physician or supplier to give estimated amounts for the individual items and/or services rather than an aggregate estimate of costs. Amounts may be provided either with the description of items and services or on the "Estimated Cost" line.

vii. Options 1 & 2 Boxes--The patient must personally select an option. Do not accept as evidence of beneficiary notice any ABN on which the physician or supplier has pre-selected an option; pre-selecting options is prohibited.

viii. In the "Date" blank, the patient, or his or her authorized representative, should enter the date on which he or she signed the ABN. If the date is filled in by the physician or supplier and the beneficiary or his or her authorized representative does not dispute the date, you should accept that date. Do not reject ABNs simply because the date is typed or printed. In the "Signature of patient …" blank, the patient, or person acting on his or her behalf, must sign his or her name.

2. Signature Requirements for ABN-G and ABN-L.--

a. The beneficiary himself or herself may sign an ABN. In the case of a beneficiary who is incapable or incompetent, his or her "authorized representative," as defined for ABN purposes in §7310.1.F, may sign an ABN. The policy enunciation in §7310.1.F of who may be an "authorized representative" supersedes the previous policy that "generally applicable rules of the Medicare program with respect to who may sign for a beneficiary apply to signing notices, including ABNs." The regulations on signature requirements for claims purposes at 42 CFR 424.36 do not apply to ABNs.

b. If the beneficiary's (or authorized representative's) signature is absent from an ABN, in case of a dispute as to the beneficiary's (or authorized representative's) receipt of the ABN, give credence to the beneficiary's (or authorized representative's) allegations regarding the ABN, except as specified in §7310.3.F.2.

c. The physician or supplier must obtain the signed and dated ABN from the beneficiary, either in person or, where this is not possible, via return mail from the beneficiary or authorized representative acting on the beneficiary's behalf as soon as possible after the ABN has been signed and dated. The beneficiary retains the patient's copy of the signed and dated ABN and returns the original. The physician or supplier retains the original ABN. These copies will be relevant on the case of any future appeal. Do not require physicians and suppliers to routinely submit copies of all ABNs to you.

F. Resolving Beneficiary Problems.--

1. A beneficiary who has been given either ABN-G or ABN-L (or the person acting on the beneficiary's behalf), may decide to receive the item or service and, in that case, should select Option 1 to indicate that he/she is willing to be personally and fully responsible for payment. When a beneficiary decides to decline an item or service, he/she should select Option 2.

There is no third option. The beneficiary cannot properly refuse to sign the ABN at all and still demand the item or service. If a beneficiary refuses to sign a properly executed ABN, the physician or supplier should consider not furnishing the item or service, unless the consequences (health and safety of the patient, or civil liability in case of harm) are such that this is not an option. If the beneficiary refuses to sign the ABN, the physician or supplier should annotate the ABN, and have the annotation witnessed, indicating the circumstances and persons involved.

2. In the case of claims to which Limitation on Liability protections under §1879(a), (b), and (c) of the Act apply, if the physician or supplier does furnish the item or service, the beneficiary's signature is meant to attest to receipt of the ABN; it has "agreement to pay" language so that it is absolutely clear to the beneficiary what the implications for him or her are. Once the beneficiary has read a properly executed ABN, he or she is "on notice;" that is, the beneficiary "knew, or could reasonably have been expected to know, that payment could not be made." The beneficiary has two legitimate choices: a) to obtain the service and be prepared to pay out of pocket, that is, personally or by any other insurance coverage, or b) not to obtain the service. If the beneficiary demands the service and refuses to pay, the physician or supplier should have a second person witness the provision of the ABN and the beneficiary's refusal to sign. They should both sign an annotation on the ABN attesting to having witnessed said provision and refusal. Where there is only one person on site (e.g., in a "draw station"), the second witness may be contacted by telephone to witness the beneficiary's refusal to sign the ABN by telephone and may sign the ABN annotation at a later time. The unused patient signature line on the ABN form may be used for such an annotation; writing in the margins of the form is also permissible. The physician or supplier should file as having given the ABN, with a GA modifier. The beneficiary will be held liable per §1879(c) of the Act in case of a denial.

3. In the case of claims to which Refund Requirement protections under §§1834(a)(18), 1834(j)(4), 1842(l), or §1879(h) of the Act apply, if the physician or supplier does furnish the item or service, the beneficiary's signature is meant to attest both to receipt of the ABN and to the beneficiary's agreement to pay. The beneficiary both must receive a properly executed ABN so that he or she is "on notice" (that is, the beneficiary "knew, or could reasonably have been expected to know, that payment could not be made") and must agree to pay. The beneficiary has the same two legitimate choices: a) to obtain the service and be prepared to pay out of pocket, that is, personally or by any other insurance coverage, or b) not to obtain the service. If the beneficiary demands the service and refuses to pay (in other words, selects Option 1 but will not sign or else marks out the agreement to pay language), the physician or supplier must take into account the fact that it will not be able to collect from the beneficiary in deciding whether or not to furnish the items or services. Although there would be little point in having a second person witness the provision of the ABN and the beneficiary's refusal to agree to pay (because the requirement that the beneficiary agree to pay still would not be fulfilled), the physician or supplier may annotate the ABN, as described in paragraph 2, above. The physician or supplier, if the items or services are furnished despite the beneficiary's refusal to pay, should file the claim using the GZ modifier, that is, as not having obtained a signed ABN, since it was not completed properly by the beneficiary. Do not hold the beneficiary liable per §§1834(a)(18), 1834(j)(4), 1842(l), or §1879(h) of the Act in case of a denial. Do hold the physician or supplier liable.

4. In either case (F.2 and F.3, above), the beneficiary who does receive an item or service, of course, always has the right to a Medicare determination and the claim must be filed with Medicare in accordance with §1848(g)(4) of the Act.

G. Demand Bills--When a beneficiary chooses Option 1 on an ABN-G or an ABN-L and receives the item or service, claims submission is mandatory; a demand bill is required. When a beneficiary chooses Option 1, the beneficiary's demand for submission of a claim and for an initial determination has been made; no further demand may be required of the beneficiary. The physician or supplier must submit a claim to you for an initial determination. On such a claim, a GA modifier must appear on the HCFA-1500 in item 24D. The GA modifier indicates that an ABN was furnished by the physician or supplier and is on file in his/her/its office and it also documents the physician's or supplier's expectation that Medicare will not pay the claim. (The GA modifier is mandatory; it must be used anytime an ABN was obtained. The use of the GZ modifier is optional. A GZ modifier may be included on the HCFA-1500 in item 24D if the physician or supplier wishes to indicate that denial for medical necessity is expected but an ABN was not obtained. Reject as unprocessable any claim line item including both the GA and GZ modifiers, as they are mutually exclusive.) Do not change your process for making an initial determination on the basis that a claim was submitted with

a GA or GZ modifier. The provision of an ABN and/or the inclusion of a GA or GZ modifier by the physician or supplier only represent the physician's or supplier's assessment that Medicare will deny payment. You must make your initial determination on the usual bases. You may not auto-deny any claim solely on the basis of a GA or GZ modifier. After you have denied payment on a claim, take into account the presence of the GA or GZ modifier in determining the liability of the beneficiary and the physician or supplier.

Exhibit 1.-- Advance Beneficiary Notice (CMS-R-131-G) for general use.
Exhibit 1S.-- Spanish Advance Beneficiary Notice (CMS-R-131-G) for general use.

Exhibit 2.-- Advance Beneficiary Notice (CMS-R-131-L) for laboratory tests.
Exhibit 2S.-- Spanish Advance Beneficiary Notice (CMS-R-131-L) for laboratory tests.

[For the online replicable copies of CMS-R-131 forms in PDF and MSWord formats, go to the CMS Beneficiary Notices Initiative (BNI) webpage at http://www.hcfa.gov/medicare/bni/. Additional information may be found at Medlearn http://www.hcfa.gov/medlearn/refabn.htm – Advance Beneficiary Notice Quick Reference Guide.]

Exhibit 1.-- Advance Beneficiary Notice (CMS-R-131-G) for general use.

Patient's Name: Medicare # (HICN):

ADVANCE BENEFICIARY NOTICE (ABN)

NOTE: You need to make a choice about receiving these health care items or services.

We expect that Medicare will not pay for the item(s) or service(s) that are described below. Medicare does not pay for all of your health care costs. Medicare only pays for covered items and services when Medicare rules are met. The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason your doctor recommended it. Right now, in your case, **Medicare probably will not pay for –**

Items or Services:
Because:

The purpose of this form is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you might have to pay for them yourself. Before you make a decision about your options, you should r**ead this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare probably won't pay.
- Ask us how much these items or services will cost you (**Estimated Cost: $**_____), in case you have to pay for them yourself or through other insurance.

PLEASE CHOOSE **ONE** OPTION. CHECK **ONE** BOX. **SIGN & DATE** YOUR CHOICE.

☐ **Option 1. YES. I want to receive these items or services.**

I understand that Medicare will not decide whether to pay unless I receive these items Or services. Please submit my claim to Medicare. I understand that you may bill me for Items or services and that I may have to pay the bill while Medicare is making its decision. If Medicare does pay, you will refund to me any payments I made to you that are due to me. If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have. I understand I can appeal Medicare's decision.

☐ **Option 2. NO. I have decided not to receive these items or services.**

I will not receive these items or services. I understand that you will not be able to submit a Claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay.

Date **Signature of patient or person acting on patient's behalf**

NOTE: Your health information will be kept confidential. Any information that we collect about you on this form will be kept confidential in our offices. If a claim is submitted to Medicare, your health information on this form may be shared with Medicare. Your health information which Medicare sees will be kept confidential by Medicare.

OMB Approval No. 0938-0566 Form No. CMS-R-131-G

Exhibit 1S.-- Spanish Advance Beneficiary Notice (CMS-R-131-G) for general use.

Nombre del paciente: No. de Medicare (HICN):

NOTIFICACIÓN PREVIA AL BENEFICIARIO DE MEDICARE (ABN)

NOTA: Usted debe tomar una decisión sobre su deseo de recibir estos servicios o productos de atención de salud.

Nosotros anticipamos que Medicare no va a pagar el (los) servicio (s) o producto (s) descrito(s) a continuación. Medicare no cubre todos los costos de atención de salud. Medicare paga sólo por los servicios y productos cubiertos cuando las reglas de Medicare son cumplidas. El hecho de que Medicare no pague por un servicio o producto determinado no significa que usted no deba recibirlo. Puede que exista una buena razón por la cual su médico se lo ha recomendado. En este momento, y en su caso particular, **es probable que Medicare no pague los siguientes exámenes:**

Servicios o Productos:
Porque:

El propósito de este formulario es ayudarle a tomar una decisión basada en su deseo de recibir estos servicios o productos, entendiendo que posiblemente tendrá que pagarlos por su propia cuenta.

Antes de tomar una decisión respecto a sus opciones, debería:

- Leer cuidadosamente este aviso en su totalidad.
- Pedirnos una explicación si no entiende por qué Medicare probablemente no pague.
- Preguntarnos cuánto le costarán a usted estos productos o servicios **Costo estimado: $_____,** en caso de que tenga que pagarlos por su propia cuenta o por medio de otro plan de seguro.

FAVOR ELEGIR UNA OPCIÓN. MARQUE UNA CASILLA. FIRME Y FECHE LA OPCIÓN SELECCIONADA.

Opción 1. SÍ. Quiero recibir estos servicios o productos.

Comprendo que Medicare no tomará una decisión respecto a si pagará o no a menos que yo reciba estos servicios o productos. Favor presentar mi reclamación a Medicare. Comprendo que esta oficina podrá enviarme una factura por estos servicios o productos y que quizás yo tenga que pagar la factura antes de que Medicare haya tomado su decisión. Si Medicare aprueba el pago, esta oficina me reembolsará cualquier pago que les haya hecho y que se me deba devolver. Si Medicare no aprueba el pago, acepto asumir personalmente la responsabilidad total por el pago correspondiente. Es decir, pagaré personalmente, ya sea con fondos propios o a través de otro plan de seguro que yo tenga. Comprendo que puedo apelar la decisión de Medicare.

Opción 2. NO. He decidido no recibir estos servicios o productos.

No recibiré estos productos o servicios. Comprendo que esta oficina no podrá presentar a Medicare una reclamación para su consideración y que yo no podré apelar a la opinión de ustedes de que Medicare probablemente no pague.

Firma del paciente o de la persona que actúe en su nombre **Fecha**

NOTA: La información sobre su salud se mantendrá confidencial. Toda información que recolectemos sobre su persona permanecerá en nuestros archivos y se mantendrá estrictamente confidencial. Si se presenta una reclamación a Medicare, la información relacionada con su salud que aparece en este formulario puede hacerse disponible a Medicare. Por su parte, Medicare mantendrá confidencial toda información sobre su salud que se haga disponible a dicha organización.

OMB Approval No. 0938-0566 Form No. CMS-R-131-G

Exhibit 2.-- Advance Beneficiary Notice (CMS-R-131-L) for laboratory tests.

Patient's Name: Medicare # (HICN):

ADVANCE BENEFICIARY NOTICE (ABN)

NOTE: You need to make a choice about receiving these laboratory tests.

We expect that Medicare will not pay for the laboratory test(s) that are described below. Medicare does not pay for all of your health care costs. Medicare only pays for covered items and services when Medicare rules are met. The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason your doctor recommended it. Right now, in your case, **Medicare probably will not pay for the laboratory test(s) indicated below for the following reasons:**

Medicare does not pay for These tests for your condition	Medicare does not pay for these tests as often as this (denied as too frequent)	Medicare does not pay for experimental or research use tests

The purpose of this form is to help you make an informed choice about whether or not you want to receive these laboratory tests, knowing that you might have to pay for them yourself. Before you make any decision about your options, you should **read this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare probably won't pay.
- Ask us how much these laboratory tests will cost you (**Estimated Cost: $**_____), in case you have to pay for them yourself or through other insurance.

PLEASE CHOOSE **ONE** OPTION. CHECK **ONE** BOX. **SIGN & DATE** YOUR CHOICE.

☐ **Option 1. YES. I want to receive these laboratory tests.**
I understand that Medicare will not decide whether to pay unless I receive these laboratory Tests. Please submit my claim to Medicare. I understand that you may bill me for laboratory Tests and that I may have to pay the bill while Medicare is making its decision.
If Medicare does pay, you will refund to me any payments I made to you that are due to me.
If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have.
I understand I can appeal Medicare's decision.

☐ **Option 2. NO. I have decided not to receive these laboratory tests.**
I will not receive these laboratory tests. I understand that you will not be able to submit a Claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay.
I will notify my doctor who ordered these laboratory tests that I did not receive them.

Date **Signature of patient or person acting on patient's behalf**

NOTE: Your health information will be kept confidential. Any information that we collect about you on this form will be kept confidential in our offices. If a claim is submitted to Medicare, your health information on this form may be shared with Medicare. Your health information which Medicare sees will be kept confidential by Medicare.

OMB Approval No. 0938-0566 Form No. CMS-R-131-L

Exhibit 2S.-- Spanish Advance Beneficiary Notice (CMS-R-131-L) for laboratory tests.

Nombre del paciente: No. de Medicare (HICN):

NOTIFICACIÓN PREVIA AL BENEFICIARIO DE MEDICARE (ABN)

NOTA: Usted debe tomar una decisión sobre su deseo de recibir estos exámenes de laboratorio.

Nosotros anticipamos que Medicare no va a pagar el (los) exámene(s) de laboratorio descrito(s) a continuación. Medicare no cubre todos los costos de atención de salud. Medicare paga sólo por los servicios y productos cubiertos cuando las reglas de Medicare son cumplidas. El hecho de que Medicare no pague por un servicio o producto determinado no significa que usted no deba recibirlo. Puede que exista una buena razón por la cual su médico se lo ha recomendado. En este momento, y en su caso particular, **Medicare probablemente no va a pagar por los exámenes de laboratorio indicados a continuación por las siguientes razones:**

Porque no se realizan normalmente dada la condición médica que usted tiene.	Porque se ha realizado con más frecuencia de lo aceptado por Medicare	Porque son exámenes experimentales o realizados con fines investigativos.

El propósito de este formulario es ayudarle a tomar una decisión basada en su deseo de recibir estos exámenes de laboratorio, entendiendo que posiblemente tendrá que pagarlos por su propia cuenta.

Antes de tomar una decisión respecto a sus opciones, debería:

- Leer cuidadosamente este aviso en su totalidad.
- Pedirnos una explicación si no entiende por qué Medicare probablemente no pague.
- Preguntarnos cuánto le costarán a usted estos exámenes de laboratorio **Costo estimado: $_____,** en caso de que tenga que pagarlos por su propia cuenta o por medio de otro plan de seguro.

FAVOR ELEGIR UNA OPCIÓN. MARQUE UNA CASILLA. FIRME Y FECHE LA OPCIÓN SELECCIONADA.

Opción 1. SÍ. Quiero recibir estos exámenes de laboratorio.

Comprendo que Medicare no tomará una decisión respecto a si pagará o no a menos que yo reciba estos exámenes de laboratorio. Favor presentar mi reclamación a Medicare. Comprendo que el laboratorio podrá enviarme una factura por estos productos o servicios y que quizás yo tenga que pagar la factura antes de que Medicare haya tomado su decisión. Si Medicare aprueba el pago, el laboratorio me reembolsará cualquier pago que les haya hecho y que se me deba devolver. Si Medicare no aprueba el pago, acepto asumir personalmente la responsabilidad total por el pago correspondiente. Es decir, pagaré personalmente, ya sea con fondos propios o a través de otro plan de seguro que tenga. Comprendo que puedo apelar la decisión de Medicare.

Opción 2. NO. He decidido no recibir estos exámenes de laboratorio.

No recibiré estos productos o servicios. Comprendo que el laboratorio no podrá presentar a Medicare una reclamación para su consideración y que yo no podré apelar a la opinión de ustedes de que Medicare probablemente no pague. Avisaré a mi médico que ordenó estos exámenes de laboratorio que no los recibí.

Firma del paciente o de la persona que actúe en su nombre **Fecha**

NOTA: La información sobre su salud se mantendrá confidencial. Toda información que recolectemos sobre su persona permanecerá en nuestros archivos y se mantendrá estrictamente confidencial. Si se presenta una reclamación a Medicare, la información relacionada con su salud que aparece en este formulario puede hacerse disponible a Medicare. Por su parte, Medicare mantendrá confidencial toda información sobre su salud que se haga disponible a dicha organización.

OMB Approval No. 0938-0566 Form No. CMS-R-131-L